Press Office
Food and Drug Administration
U.S. Department of Health and Human Services

FDA STATEMENT
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Media Inquiries: Catherine McDermott
301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA-Requested Recall - Cytosol Laboratories, Inc.
Product Contains Dangerous Levels of Endotoxin

The U.S. Food and Drug Administration (FDA) today delivered a letter to Cytosol Laboratories, Inc., of Braintree, Mass., to request a recall of all brands and sizes of Balanced Salt Solution (BSS) that the firm manufactures. BSS is a drug used by health professionals to irrigate a patient's eyes, ears, nose and/or throat during a variety of surgical procedures including cataract surgery.

FDA requested the recall because product lots were found to have elevated levels of endotoxin. Endotoxins, also known as pyrogens, are substances found in certain bacteria that cause a wide variety of serious reactions such as fever, shock, changes in blood pressure and in other circulatory functions. FDA has received reports of a serious and potentially irreversible eye injury called Toxic Anterior Segment Syndrome(TASS) which occurs when a contaminant, such as endotoxin, enters the anterior segment of the eye during surgery and causes an inflammatory reaction. FDA has also received complaints relating to injuries in over 300 patients who were given BSS manufactured by Cytosol Laboratories, Inc.

The FDA requests that the company take immediate action to retrieve all inventories of the product, including any existing stock at physician offices and hospitals. An FDA-requested recall is initiated to protect the public health when a product that has been distributed represents a risk of illness or injury and the firm has not initiated a recall of the product. FDA is instructing hospitals, physicians, and consumers to immediately stop using any of these products, quarantine any remaining product, and if no return instructions from Cytosol are received, destroy the product.

An estimated one million units of BSS products were distributed between December 2003 and December 2005. The BSS products subject to the recall order were manufactured by Cytosol Laboratories, Inc. for distribution under three labels:

- "AMO Endosol" distributed by Advanced Medical Optics, Inc. (AMO), Santa Ana, Calif.;
- "Cytosol Ophthalmics" distributed by Cytosol Ophthalmics, Lenoir, NC; and
- "Akorn" distributed by Akorn, Inc., Buffalo Grove, Ill.

Individuals with questions may call FDA at 1-888-463-6332. Any adverse reactions or problems experienced with the use of this product should also be reported to the FDA MedWatch Program by completing a form online on the MedWatch web site at www.fda.gov/medwatch/report.htm, by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

AMO Recall release:
http://www.eyeworld.org/ewweek.php?id=394&query=amo%20recall#2

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